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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,020	10/05/2001	Hiroshi Sano	026350-068	3752

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

17

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/971,020	SANO ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 20 is/are allowed.
- 6) ☒ Claim(s) 19, 21-27, and 32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. *See form PTO 948, mailed on 9/24/02, as part of Paper #10*
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice To Comply</u> |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the abstract is withdrawn, in light of its amendment.
3. The objection to the brief descriptions of Figures 2 and 6 is withdrawn, in light of their amendment.
4. The objections to claims 18-27, 32, and 33 are withdrawn, in light of the claim amendments.
5. The rejection of claims 18-21 under 35 U.S.C. 101 is withdrawn, in light of the claim amendments.
6. The rejections of claims 20-27, 32, and 33 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim amendments.
7. The rejection of claims 18-21 under 35 U.S.C. 102(a) is withdrawn, in light of the submissions of the certified foreign priority document and an English-language translation.

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8. The rejection of claims 18, 20, 22, 23, 25, 32, and 33 under 35 U.S.C. 102(b) is withdrawn, in light of the claim amendments.

9. The rejection of claims 18-27, 32, and 33 under 35 U.S.C. 103(a) is withdrawn, in light of the claim amendments and submissions of the certified foreign priority document and its English-language translation.

Priority

10. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), namely certified Japan Application 2000-307, 146 (filed 06 October 2000), and its English-language translation, which papers have been placed of record in the file.

Drawings

11. On page 3 of the paper received 24 April 2003, Applicants comment that it was agreed during a teleconference that the corrections to drawings, outlined by the Draftsperson in the Form PTO 948, would be deferred to a later date. Applicants continue, stating, "Should allowable subject matter be found and should the Examiner determine such corrected drawings are indeed necessary, he will so state at least in Box 10 of an Office Action Summary and preferably in the Detailed Action as well." (response, page 3, 2nd full paragraph). While Applicants were allowed to defer the submission of corrected drawings, they should not misinterpret this as a waiving of the requirement for submitting corrected drawings. Applicants are required to submit corrected drawings.

Specification

12. The specification was objected to in Office action mailed 24 September 2002, for failing to identify sequences appearing in Figures 2, 3, and on page 7, by sequence identifiers, as required by 37 CFR 1.821-1.825. Applicants, in the papers received 24 April 2003 and 24 January 2003, have inserted sequence identifiers in the appropriate locations of the specification. However, it is noted that while the sequence identifiers inserted into page 7 refer to SEQ ID NOs: 9-22, the sequence listing only contains SEQ ID NOs: 1-8. Applicants are required to submit new paper and computer-readable copies of the sequence listing, including the sequences of SEQ ID NOs: 9-22. Please see the attached Notice to Comply. The time period for response to comply with sequence rules 37 CFR 1.821-1.825 will run concurrently with the response time to the instant Office action.

Claim Objections

13. Claim 33 is objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112

14. Claims 19, 21-27, and 32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 24 September

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2002 under item 9. Applicants traverse the rejection in the paper filed 24 January 2003.

Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the specification states that genes whose base sequences have 10 or less deletions, substitutions, or additions to the base sequence of SEQ ID NO: 2; exhibit 90% or more identity/homology to the base sequence of SEQ ID NO: 2; and encode a polypeptide that catalyzes biosynthesis of theobromine using 7-methylxanthine as the substrate are part of the invention, and that armed with this knowledge, one skilled in the art would reasonably conclude that Applicants had possession of the claimed invention (response, paragraph bridging pages 6-7 and page 7, 1st full paragraph). However, the specification does not correlate the activity of SEQ ID NO: 1 with any other amino acid sequence. As discussed in the Office action mailed 24 September 2002, Ogawa et al. teach that enzymes involved in caffeine synthesis have a rather strict substrate specificity arising from the diversity of a few amino acids. The specification does not teach the amino acids of SEQ ID NO: 1 that can be changed without altering its functional activity and substrate specificity.

15. Claims 19, 21-27, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for genes that encode amino acid sequences that differ from SEQ ID NO: 1 and have the activity to biosynthesize theobromine from 7-methylxanthine and all methods to produce transformed plants in which expression of the claimed gene is decreased and biosynthesis of theobromine is inhibited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope

with these claims, for the reasons of record stated in the Office action mailed 24 September 2002 under item 9. Applicants traverse the rejection in the paper filed 24 January 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the specification provided that one may delete, add, or substitute no more than 10 bases from SEQ ID NO: 2, must have 90% homology/identity or more to SEQ ID NO: 2, and must have activity of catalyzing biosynthesis of theobromine using 7-methylxanthine as the substrate, and that one of skill in the art could readily practice the invention by modifying SEQ ID NO: 2, based on the detailed parameters provided (response, page 8, last paragraph). However, the specification does not provide any guidance as to what amino acids of SEQ ID NO: 1 may be changed without altering its function. Amino acid sequences that have 90% identity with SEQ ID NO: 1 differ in 38 amino acid residues. Yet, as discussed, Ogawa et al. teach that a few amino acids determine substrate specificity. The specification provides no guidance to the identity of amino acid residues of SEQ ID NO: 1 that can be changed. Further, it is noted that a change of no more than 10 bases in SEQ ID NO: 2 will yield a sequence that has greater than 99% identity with SEQ ID NO: 2, not 90%.

Regarding claims 22 and 32, Applicants argue that one skilled in the art could readily utilize any art-recognized technique for inhibiting expression, and need not use only the techniques listed in the specification (response, page 9, 1st paragraph). However, the specification provides no guidance whatsoever as to how other techniques can be practiced with the claimed nucleotide sequences. The specification does not teach any dominant mutants, products that will block the activity of SEQ ID NO: 1, products that will block transcription of the claimed sequences, etc. See also Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001,

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1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. It is again suggested that the claims be amended to indicate that theobromine synthesis is decreased by expressing the claimed nucleotide sequence in antisense orientation, or by co-suppression.

Summary

16. Claims 18 and 20 are allowed, claim 33 is objected to, and claims 19, 21-27, and 32 remain rejected.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

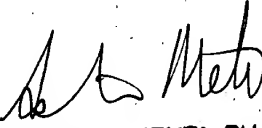
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 2, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER